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Minnesota Board of Pharmacy

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Published to promote voluntary compliance of pharmacy and drug law.

Disciplinary Activity

The Minnesota Board of Pharmacy took the following disciplinary actions concerning **pharmacists** between the dates of April 1, 2007 and June 15, 2007.

Connell, Julie. License #115359. Ms Connell admitted to engaging in an inappropriate relationship with a patient. She was reprimanded and placed on probation, for an indefinite period of time, until she successfully completes a professional boundaries course approved by the Board. She was also assessed a $500 civil penalty.

Gruenhagen, Bruce. License #114458. Mr Gruenhagen successfully completed his probation and the Board granted his petition for an unrestricted license.

Raths, Kathryn. License #114856. Ms Raths admitted to the theft of controlled substances from her employer and the unauthorized personal use of those drugs. Her license was suspended, but the suspension was stayed and she was placed on probation for three years or until she successfully completes a participation agreement with the Health Professional Services Program (HPSP), whichever is later. She was also assessed a $500 civil penalty.

Samuelson, Donald. License #113507. Mr Samuelson successfully completed his probation and the Board granted his petition for an unrestricted license.

Warren, Todd. License #115234. Mr Warren successfully completed his probation and the Board granted his petition for an unrestricted license.

The Board took the following disciplinary actions concerning **technicians** between the dates of April 1, 2007 and June 15, 2007.

The following pharmacy technicians had their registrations suspended:

- **Tilseth, Sherry, Registration #712920**
- **Bayuk, Alexandria, Registration #713951.**

Klass, Oren K. Registration #700266. The Board issued an order rescinding the Order of Revocation that the Board issued earlier this year. The effect of the Rescission Order is to render the Revocation Order null and void. Therefore, Mr Klass has a technician registration that is clear from any disciplinary action.

Governor Pawlenty Appoints Two to Board of Pharmacy

On May 16, 2007, Governor Tim Pawlenty announced the appointment of Karen Bergrud, and the reappointment of Carleton Crawford to the Board of Pharmacy. Both are appointed to four-year terms that expire January 3, 2011.

Ms Bergrud, of Stewartville, has over 28 years of experience in the pharmacy field. She is the assistant director of pharmacy operations at Mayo Clinic in Rochester. In addition to her duties at Mayo, she is responsible for the operations of the central and satellite pharmacies at Saint Mary's and Rochester Methodist hospitals. She received her bachelor of science degree in pharmacy from the University of Minnesota. She is a member of the Minnesota Society of Health-System Pharmacists. Ms Bergrud is appointed as a pharmacist member and replaces Mr Vernon Kassekert on the Board.

Mr Crawford, of Minneapolis, is the project manager and treasurer for C^3 Home Design Inc, in Minneapolis. He previously worked as a designer, drafter, and project manager for Shea Architects Inc. He received a master of architecture degree from the University of Minnesota and a bachelor of arts degree in economics from Carlton College in Northfield. Mr Crawford is reappointed as a public member of the Board.

Board Seeks Applicants for Surveyor Position

The governor and the Minnesota State Legislature approved the Board's request for authority to create a new pharmacy surveyor (Inspector) position. The Board is now seeking applicants for the new position. Applicants must be licensed to practice pharmacy in Minnesota, or must qualify to obtain such licensure. At least five years of experience as a licensed pharmacist is desirable. Travel throughout the state is required. Pharmacists interested in applying for this position should contact the Board of Pharmacy for an application.

FDA Issues Guidance on Glycerin Testing to Prevent DEG Poisoning

Spurred to action by repeated instances of diethylene glycol (DEG) poisoning, Food and Drug Administration (FDA) recently issued a guidance for industry entitled "Testing of Glycerin for Diethylene Glycol." This guidance provides recommendations on testing that will help pharmaceutical manufacturers, repackers, and other suppliers of glycerin, and pharmacists who engage in drug compounding, to avoid the use of glycerin that is contaminated with DEG and prevent incidents of DEG poisoning.

DEG contamination of glycerin can be detected by using specific analytical test procedures described in the United States Pharmacopeia monograph for glycerin, which quantifies the amount of DEG present at a detection level of 0.1%, as recommended by the interagency Diethylene Glycol Contamination Prevention Workshop of 1997. The guidance is available on the FDA Web site at *www.fda.gov/cder/guidance/7654fnl.htm.* FDA is accepting electronic comments on the guidance at *www.fda.gov/dockets/ecomments.*

Improperly Compounded Colchicine Blamed for Recent Deaths

Compounded colchicine that was 10 times as potent as labeled was responsible for two recent deaths in Oregon and Washington, the *Portland Tribune* reported on April 27, 2007. State officials are investigating the drug's role in a third death, also in Oregon. The drug was sent to a Portland, OR, clinic by ApothéCure, Inc, a Dallas, TX-based compounding pharmacy that distributes its drugs throughout the country. The two patients who died had received injections of colchicine as a treatment for back pain. Lab tests revealed that the colchicine administered in the two deaths had a potency of 4 mg/ml, rather than the 0.5 mg/ml stated on labels. According to Gary A. Schnabel, executive director of the Oregon State Board of Pharmacy, ApothéCure, a licensed Texas pharmacy, may be operating as a manufacturer. Both the Oregon Board and the Texas State Board of Pharmacy have opened investigations into the incident. The Texas Board advised ApothéCure to stop making colchicine; the company agreed, the *Portland Tribune* reported. On May 2, FDA announced the recall of all strengths, sizes, and lots of injectable colchicine compounded and sold by ApothéCure within the last year. The FDA MedWatch Safety summary on this issue is available at *www.fda.gov/medwatch/safety/2007/safety07.htm#Colchicine.*

New Podcasts Provide Emerging Drug Safety Information

FDA recently supplemented its print- and Web-based public health advisories with the launch of an audio broadcast service providing emerging drug safety information. The broadcasts, commonly known as podcasts, can be transmitted to personal computers and personal audio players. The service is part of FDA's ongoing effort to broaden and speed its communications on the safety of marketed medications when unexpected adverse events are reported to FDA. Since FDA launched the service in February 2007, broadcasts have addressed the potential hazards of local anesthetics used in hair removal; the voluntary market withdrawals of drugs to treat the symptoms of Parkinson's disease and irritable bowel syndrome; and serious adverse events associated with agents that reduce the need for blood transfusions in cancer patients. The broadcasts are available on the FDA Web site at *www.fda.gov/cder/drug/podcast/default.htm.*

Prevent Tragedies Caused by Syringe Tip Caps

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

Over the past several years, there have been a number of reports where children have swallowed or choked on hypodermic syringe caps that were overlooked by parents and left on the syringes administering the medication. In 2001, a 5-month-old child asphyxiated when a cap from a Becton Dickinson 3 ml hypodermic syringe ejected into his throat during medication administration. In this case, a pediatrician provided the parents with the hypodermic syringe (without the needle) to administer Vantin® (cefpodoxime) suspension. With the cap intact, the father inserted the syringe into the Vantin, pulled back the plunger, and the medication flowed into the syringe. To him, the cap appeared to be part of the syringe. When he placed the syringe containing the medication into the baby's mouth, the cap flew off and became lodged in his airway. The baby was taken to the hospital where a procedure was performed to remove the cap; however, he did not survive.

Despite these reports, the mother of a 9-month-old child recently notified the Institute for Safe Medication Practices about a near fatal experience involving her child. Her community pharmacist gave her a parenteral syringe (without the needle) to help her accurately measure and administer an oral rehydration liquid for her daughter. Unfortunately, the pharmacist's good intention resulted in patient harm. The mother was unaware that the syringe tip held a small, translucent cap; however, despite this, she was able to withdraw the oral liquid. Then as she administered the liquid, the cap on the end of the syringe ejected and became lodged in the child's throat, causing airway obstruction. Fortunately, the child recovered.

Although parenteral syringes are not designed for oral administration, health care practitioners may provide them to patients or caregivers to measure oral liquids without realizing how dangerous this practice may be. Some syringe

manufacturers place the small, translucent caps on parenteral syringes packaged without needles as a protective cover. However, practitioners may not realize the cap is there or may not inform patients or caregivers of the need for its removal prior to use. The danger arises due to the fact that the cap does not provide a good seal. Subsequently, medications can be drawn into many of these syringes without removing the caps. If not removed before administration, the force of pushing the plunger can eject the cap and cause it to lodge in a child's trachea.

Safe practice recommendations: Consider the following strategies to help protect your patients from tragedies caused by syringe tip caps.

- **Increase awareness.** Share this and previous errors with staff to illustrate why parenteral syringes should never be used for oral liquid medications. Show staff a video from FDA and ISMP highlighting this issue (access the video link at: *www.accessdata.fda.gov/scripts/cdrh/cfdocs/psn/transcript.cfm?show=3#6*).
- **Product availability.** Ensure that **oral** syringes (without caps) or other appropriate measuring devices are readily available for distribution or purchase at your practice site. Verify that the dosage can be accurately measured using the oral syringe. It may be necessary to keep a few different sizes on hand to ensure proper measurement of smaller doses.
- **Limit access.** If parenteral syringes must be stocked for use with injectable products, purchase syringes that are not packaged with the translucent caps to minimize the likelihood of this error.
- **Warning labels.** Add warning labels that state, "not for use with oral liquids" to boxes or storage bins containing parenteral syringes.
- **Educate patients and caregivers.** Provide education to patients and caregivers regarding proper use of an oral syringe (or other measuring device). Demonstrate how to measure and administer the dose and inform them about how to clean the device, if it is to be reused. Several years ago, Becton Dickinson voluntarily elected to package parenteral syringes without the small caps in response to this serious issue. However, since some manufacturers still include a cap on parenteral syringes, the danger of asphyxiation with the cap is still present. We have again contacted FDA to alert them about this problem. They have stated that they will be following up with each syringe manufacturer with the goal to get the syringe caps removed. At the very minimum, we believe that the packaging of parenteral syringes should be required to clearly state, "not for oral use" or "not for use with oral liquids."

New FDA Web Page Warns Against Buying Isotretinoin Online

FDA has launched a special Web page to warn consumers about the dangers of buying isotretinoin online. Improperly used, isotretinoin can cause severe side effects, including birth defects and serious mental health problems. The Web page, *www.fda.gov/buyonline/accutane*, is positioned as a search result on Internet search engines when consumers initiate an online search for the drug under any one of its four names (isotretinoin is sold under the brand name of Accutane® and in generic versions called Amnesteem™, Claravis™, and Sotret®). The Web page warns that the drug "should only be taken under the close supervision" of a physician and a pharmacist, and provides links to related information, including ways to check that drugs purchased online come from legitimate pharmacies.

To reduce risks, FDA and the manufacturers of isotretinoin have implemented a strict distribution program called iPLEDGE to ensure that women using isotretinoin do not become pregnant, and that women who are pregnant do not use isotretinoin. Isotretinoin is available only at pharmacies that are registered for this distribution program. Additionally, the distribution program is designed to prevent the sale of isotretinoin over the Internet. Dispensing must comply with the agency's risk management requirements.

Tampering Results in Misbranding of Ziagen as Combivir

GlaxoSmithKline and FDA warned health care professionals of an apparent third-party tampering that resulted in the misbranding of Ziagen® as Combivir® and employed counterfeit labels for Combivir tablets. Two 60-count misbranded bottles of Combivir tablets contained 300 mg tablets of Ziagen.

The counterfeit labels identified are Lot No. 6ZP9760 with expiration dates of April 2010 and April 2009. The incident appears to be isolated and limited in scope to one pharmacy in California.

Pharmacists are advised to immediately examine the contents of each bottle of Combivir in their pharmacies to confirm that the bottles contain the correct medication. If a bottle contains anything other than Combivir tablets, pharmacists are advised to notify the manufacturer.

The letter from GlaxoSmithKline and FDA, containing photos of actual Combivir and Ziagen tablets, is posted on the FDA Web site at *www.fda.gov/medwatch/safety/2007/Ziagen_Dear_RPh_03-29-2007.pdf*.

FDA Issues Halt on Manufacture, Distribution of Unapproved Suppository Drugs

FDA notified health care professionals and consumers that companies must stop manufacturing and distributing unapproved suppository drug products containing trimethobenzamide hydrochloride.

These products, used to treat nausea and vomiting in adults and children, have been marketed under various names, including Tigan®, Tebamide™, T-Gen, Trimazide, and Trimethobenz. Drugs containing trimethobenzamide in suppository form lack evidence of effectiveness. This action does not affect oral capsules and injectable products containing trimethobenzamide that have been approved by FDA.

FDA urges consumers currently using trimethobenzamide suppositories or who have questions or concerns to contact their health care professionals. Alternative products approved to effectively treat nausea and vomiting are available in a variety of forms.

The MedWatch safety summary and a link to the full press release are available at *www.fda.gov/medwatch/safety/2007/safety07.htm#trimethobenzamide*.

Adoption of Rules Package

The Board of Pharmacy worked for over two years to update rules in many different areas. On Monday, May 14, 2007, a "Notice of Adopted Permanent Rules Relating to Pharmacy Regulations" was published in the *Minnesota State Register*. The rule changes originally proposed by the Board were published on October 2, 2006. Revisions to the language that was originally proposed were published on May 14, 2007. The two documents published in the *State Register*, taken together, comprise the official version of the rule changes. The rule changes listed in those two official documents went into effect on May 21, 2007.

Board staff has combined the two official documents into an unofficial, complete draft of rule changes that should be easier to follow. All three of those documents can be viewed on the Board's Web site at *www.phcybrd.state.mn.us/rulemake06.htm.* Pharmacists, technicians, interns, and other persons working for businesses licensed by the Board are strongly encouraged to review the new rules.

Specific rule changes will be highlighted in the Board's *Newsletter,* starting with this edition. Information about rule changes concerning quality assurance and counseling is provided below.

Certification and Quality Assurance

Pharmacists are reminded that there is a difference between certification and quality assurance, and that both are required per Minnesota Rules. Certification is the process by which one pharmacist or pharmacist-intern takes responsibility for ensuring that a prescription has been accurately filled and that a prospective drug utilization review has been completed. In certifying the completed prescription, the pharmacist or pharmacist-intern must:

A. check the original labeled container from which the medication was withdrawn;
B. check the labeling on the container in which the drug is to be dispensed;
C. check the contents of the container in which the drug is to be dispensed and the appearance of the total product;
D. review the patient's medication profile for purposes of conducting a prospective drug review and checking the accuracy of the addition to the profile of the medication dispensed; and
E. initial the prescription or other permanently maintained record.

Pharmacists using automated medication management dispensing systems must develop written policies and procedures, which provide that all certification steps are performed and documented before the medication is distributed to the patient. These policies and procedures must be available for inspection by the Board.

The Board's quality assurance rule requires pharmacies to have a procedure in place to ensure that prescription data is correctly entered into computers. A pharmacy must implement a written quality assurance plan that includes the pharmacist comparing the original written prescription or an image of the original written prescription, to the information entered into the computer, and documenting the completion and accuracy of this comparison with the date and initials of the pharmacist completing the task. This process must not occur prior to two hours after the prescription has been initially certified, unless it is completed by a second individual pharmacist as soon as possible after the initial certification has occurred. The process must be completed within 72 hours.

As an alternative, hospitals providing inpatient pharmacy services may elect instead to develop a plan to provide safeguards against errors being made and perpetuated due to inaccurate prescription data being entered into the pharmacy's computer. This written quality assurance plan must be made available to the Board surveyors upon request.

Counseling

Upon receipt of a new prescription or a new drug order, following a review of the patient's record, a pharmacist must personally initiate discussion of matters, which in the professional judgment of the pharmacist will enhance or optimize drug therapy with each patient or the agent or caregiver of the patient. It is no longer acceptable for a designee, such as a clerk or technician, to make the offer to counsel on the pharmacist's behalf. Instead, the pharmacist must personally initiate the counseling process. A patient has the right to refuse the pharmacist's offer to counsel, but such refusal should be documented.

The counseling must be in person, whenever applicable, may be supplemented with written material, and must include appropriate elements of patient counseling, including:

1. the name and description of the drug;
2. the dosage form, dose, route of administration, and duration of drug therapy;
3. intended use of the drug and expected action;
4. special directions and precautions for preparation, administration, and use by the patient;
5. common severe side effects, adverse effects, or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
6. techniques for self-monitoring of drug therapy;
7. proper storage;
8. prescription refill information;
9. action to be taken in the event of a missed dose; and
10. pharmacist comments relevant to the patient's drug therapy, including any other information peculiar to the specific patient or drug.

The pharmacist must counsel the patient on a refilled prescription if deemed necessary according to the pharmacist's professional judgment. The consultation must be in person whenever applicable.

The *Minnesota Board of Pharmacy News* is published by the Minnesota Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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